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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,779

05/22/2007

Klaus Breddam

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

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DELIVERY MODE

02/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,779	Applicant(s) BREDDAM ET AL.	
	Examiner Medina A. Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-85 is/are pending in the application.
- 4a) Of the above claim(s) 79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-78 and 80-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

**The Office action of 10/15/09 has been vacated in favor of this new non-final
action**

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 56-78 and 80-85 in the reply filed on 07/20/09 is acknowledged. The requirement is made Final.

Claims 56-85 are pending.

Claim 79 is withdrawn from consideration as being directed to the non-elected invention.

Claims 56-78 and 80-85 are examined.

The international Preliminary examination report filed in this application has been considered.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with

Art Unit: 1638

the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/800,200, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The specific ratio in the beverage of claims 73 and 75 are not described in the parent application. Therefore, the effective filing date of claims 73 and 75 (and dependents) are considered to be 05/22/07.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56-78 and 80-85 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Douma et al (WO 2002053721; Applicant's IDS).

The claims are drawn to a plant product produced from a barley plant or part thereof having a mutation in the LOX-1 gene causing a total loss of LOX-1 activity; said plant product is a malt or wort composition; said composition is prepared using enzyme composition; said plant product is a beverage obtained by manufacturing the barley plant or part thereof having mutation in the LOX-1 gene causing a total loss of LOX-1 activity; said beverage is a beer prepared using malt from kernels of said barley plant or from wort composition; wherein the gene encoding LOX-1 comprises a nonsense codon corresponding to base position 3572-3574 of SEQ ID NO: 2 or a splice mutation corresponding to nucleotide position 2311 of SEQ ID NO: 6; a beverage having stable organoleptic qualities with ratio of 9, 12, 13-trihydroxyoctadecenoic acid to 9, 10, 13-trihydroxyoctadecenoic acid within the beverage is at most 1.8 and comprises at most 0.05ppb free trans-2-nonenal (T2N) after incubation at 37C and 4 to 6 ppm sulfite. The claims are also drawn to a method of producing a food composition, feed composition, a malt or wort using a barley plant or part thereof having a mutation in the LOX-1 gene causing a total loss of LOX-1 activity; said method comprising preparing a malt composition from kernels of the barley plant and processing it by mashing and adding it a LOX-inhibitor during mashing; said method wherein the malt composition has no LOX-1 activity.

Art Unit: 1638

Douma et al teach plant products including wort and malt compositions prepared from barley plant or part thereof expressing mutant LOX-1 protein, and beverages particularly beer prepared from said malt having increased stability and reduced T2N potential; said plant characterized by a reduction or absence of lipoxygenase activity; said beverage having a reduced content T2N so that flavor stability during storage at high temperature is improved; the sulfite content of the beer is controlled below 5ppm. Said beverage is a beer with stable organoleptic properties. Douma et al also teach that the plant products are prepared from the barley plant and parts thereof including germinating grain having greatly reduced LOX-1 activity using enzymatic methods. The cited reference teaches a method of producing plant products such as wort and malt prepared from Lox-1 mutated line G barley plant having greatly reduced LOX-1 due to a single mutation (from glycine to aspartic acid) at amino acid position 368 of SEQ ID NO: 12; and methods of preparing beverages from said wort and malt products by brewing methods (see example 6); wherein the beer brewed from LOX-1 mutated plant line G contains from 0.005 ppb to 0.025 ppb of T2N at 37 C and from 1-2.5 mg/ml of SO₂ (Table 3 on page 44) . The organoleptic qualities with ratio of 9, 12, 13-trihydroxyoctadecenoic acid to 9, 10, 13- trihydroxyoctadecenoic acid within the beverage that is 1.8 would be an inherent property. See also Tables 4-7 on pages 45-46. The addition of LOX inhibitor during brewing would render the claimed non-obvious, given that the barley plant has no LOX-protein activity. Also, Claims 1, 17-27 of Douma et al are drawn to plant products prepared from barley having reduced or no LOX-1

Art Unit: 1638

protein activity ; malt, wort and beverages including beer prepared from said plant product (see the whole document) .

It appears that the claimed plant products including malt, wort and beverages may be the same as the prior art malt, wort and beverages disclosed by Douma et al. Hence, the instantly claimed plant products are indistinguishable from the prior art plant products. Since Applicant has not disclosed sufficient specific structure/compositions or any other specific properties that would distinguish the claimed plant products, the claimed plant products are deemed to be anticipated by or obvious over the prior art plant products. MPEP states "(w)here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 1638

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56-71 and 76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-11 of U.S. Patent No. 6, 660,915 (Applicant's IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both the application and patent are drawn to a plant product that is malt or beer beverage that is prepared from a barley plant with mutated LOX-1 protein and reduced or no LOX-1 activity, and a method of producing said plant products. The claims of the application are drawn to plant products including wort and malt and beverages prepared from said malt and wort products; said plant products prepared from barley plant having a mutation in the LOX-1 gene causing a total loss of LOX-1 activity and a method of producing said products. The claims of the patent are drawn to plant products prepared from a barley plant having mutation in LOX-protein having the specific amino acid sequence of SEQ ID NO: 12, wherein the plant has reduced or no LOX-1 activity. The claims of the application are genus claims encompassing the invention claimed in the patent. Therefore, since genus is obvious over a species encompassing said genus, the invention claimed in the

Art Unit: 1638

application is obvious over the invention claimed in the patent, absent evidence to the contrary.

Claims 56-72 and 76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-13 of U.S. Patent No. 7, 420,105 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both the application and patent are drawn to a malt composition prepared from a barley plant with mutated LOX-1 protein and with no LOX-1 activity. The claims of the application are drawn to plant products including malt prepared from a barley plant having a mutation in the LOX-1 gene causing a total loss of LOX-1 activity; wherein the gene encoding LOX-1 comprises nonsense codon at position 3571-3574 of SEQ ID NO: 2 or splice site mutation at position 2311 of SEQ ID NO: 6. In both the application and the patent, SEQ ID NO: 2 encodes SEQ ID NO: 3, and SEQ ID NO: 6 encodes SEQ ID NO: 7. The claims of the patent are drawn to a malt composition comprising malted kernels of a barley plant having mutated LOX-protein in the amino acids 520 to 862 of SEQ ID NO: 3 or 7, wherein the plant has no LOX-1 activity. The mutations in the nucleic acid of the application claims are obvious over the mutations of the proteins in the patent claims. The resultant products are also identical since they are prepared from barley plant with no LOX-activity, absent evidence to the contrary.

Remarks

No Claim is allowed.

Contact Information

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
2/18/2010

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638